Ionone Derivatives Category - Comments of Environmental Defense

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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Ionone Derivatives Category.

The Terpene Consortium (representing 21 companies of the Flavor and Fragrance High Production Volume Consortia) proposes to handle two substances, methylionone and iso-methylionone, as a category termed "Ionone Derivatives." These chemicals have closely related chemical structures and may exist in alpha-, beta, or gamma- configurations depending upon the position of the double bond at the 1, 2 or 2(exocyclic) location of the cyclohexane ring. Both compounds occur naturally and are produced in significant volumes through synthetic methods. The sponsor states that both are used primarily in fragrances and food flavorings.

In support of this proposal the Terpene Consortium has submitted a thorough and well organized Test Plan that effectively summarizes a well-organized Robust Summary. The Robust Summary effectively presents a compilation of experimental and calculated data describing the chemical/physical properties, environmental fate and toxicology of various members of the category. Given the close similarity of the chemical structures and properties of these chemicals, we support their consideration as a chemical category.

All available and calculated data describing or predicting the chemical properties and fate of methylionone and iso-methylionone indicate they readily degrade under normal environmental conditions and thus do not accumulate or persist in the environment. Calculated photodegredation half-lives are less than one hour. Methylionone and iso-methylionone are stable in pure water but are degraded by microorganisms. They have low toxicity to fish. These chemicals were among a group of 21 chemicals reviewed by the Joint Expert Committee on Food Additives in 1999 and recognized as safe under current conditions of use. They are also among those chemicals Generally Recognized as Safe (GRAS) for their intended use by the US Food and Drug Administration.

When consumed by higher animals and humans methylionone and iso-methylionone are rapidly metabolized to polar metabolites and excreted. Both compounds have low acute toxicity to mammals. Neither chemical appears to have appreciable genotoxicity. Our review of data from repeat-dose studies indicates that, as might be expected of substances with strong flavoring properties, repeat dosing in food is limited by palatability. Nevertheless, available data from such studies indicate a no-effect level of 10 mg/kg and minimal adverse effects at 100 mg/kg. Results of repeat-dose studies and studies of reproductive toxicity studies of these chemicals indicate they appear to have little or no potential to cause adverse effects on reproduction and/or development. The Test Plan indicates that data requested for these chemicals are available (and have been described in the robust summary), can be bridged from closely related chemicals, or have been calculated. For aquatic invertebrates and plants, the Test Plan calls for calculated data to be confirmed by experimental data for iso-methylionone.

In summary, we find this to be a carefully prepared Robust Summary/Test Plan that clearly and concisely summarizes available data and proposes additional testing on aquatic invertebrates and plants to confirm some calculated data. Thus, we consider the Robust Summary/Test Plan submitted for methylionone and iso-methylionone acceptable as submitted.

Thank you for this opportunity to comment.

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